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DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

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Date: March 21, 2000

To: Dockets Management Branch (HFA-305)

From: Melissa Lamb
Office of Generic Drugs

Subject: Current Regulatory and Legislative Issues for API Manufactures

This memorandum forwards overheads of a presentation to the Dockets Management Branch for inclusion in Docket 90S-0308. The following is information on the presentation for the Docket records:

Title of Presentation: 180-Day Generic Drug Exclusivity for ANDAs Proposed Rule

Presented for: NAPM Workshop-Seminar, New York City

Date Presented: 3/21/200

Presented by: Cecelia M. Parise, R.Ph.

Number of Pages: 11

Melissa Lamb

Attachment

90S-0308

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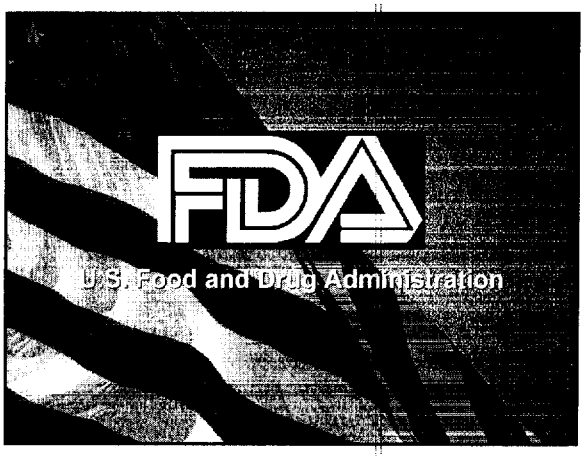

NAPM
Current Regulatory and Legislative Issues for API Manufactures
March 21, 2000

180-Day Generic Drug Exclusivity for ANDAs Proposed Rule

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180-Day Generic Drug Exclusivity

- August 6, 1999 - Proposed Rule Published
- November 4, 1999 - Comment Period Closed
- Number of Persons Submitting Comments = 19

Previous Regulation
21 CFR 314.107(c)

- First
- Sued
- Win

How did we arrive here?

- Previous regulation was successfully challenged in the courts
  - *Mova Pharmaceutical Corp v. Shalala, 1998*
  - *Granutec, Inc. v. Shalala, 1998*

What is FDA's Current Policy?

- Outlined in Guidance For Industry Published June, 1998
- "Successful defense" provision removed, FR Notice - November 5, 1998

Who is Currently Eligible for 180-day Exclusivity?

- First Application with a PIV certification
  - Substantially Complete
  - Received

Who is Eligible Under the Proposed Rule?

- Only the First Applicant is Eligible
  - Substantially Complete
  - Received
    - 4 in favor
    - 4 oppose
    - 11 no comments

What is a Substantially Complete Application?

- Contains all required information under the Food Drug and Cosmetic Act and the Regulations
- Contains all required bioequivalence studies

What if the Bioequivalence Study Fails?

- If study fails and needs to be repeated, firm no longer eligible for exclusivity.
- No other applicant eligible
  - 1 in favor
  - 6 oppose
  - 12 no comment

What is the Purpose of this Policy?

- Prevents the submission of incomplete or failed bioequivalence studies in order to obtain first to file status
  - Congress and Industry expressed concerns regarding "sham" applications

Rolling Exclusivity

- The next applicant in line is eligible if the first applicant is disqualified
  - 9 in favor
  - 4 oppose
  - 6 no comment

Product Based Exclusivity vs. Patent Based Exclusivity

- Patent based delays generic entry and administration is complex
  - 3 in favor
  - 2 oppose
  - 14 no comment

Shared Exclusivity for Multiple ANDA's Received on the Same Day

- Exclusivity period shared
- First applicant granted 180-day exclusivity starts the clock
  - 1 in favor
  - 4 oppose
  - 14 no comment

Why Share Exclusivity?

- Fairness
  - First Applicant not determined by clerical personnel
  - East Coast/West Coast Considerations
  - Logistics - Velvet Rope
- Encourages the submission of quality applications

What is a Triggering Period?

- Length of time after the tentative approval of a subsequent application
- 180 days or
- 60 days - First application has final approval and there is no legal barrier to marketing
- Distinct from 180-day Exclusivity Period

Why is FDA Proposing the Triggering Period?

- Limits the time first application blocks approval of subsequent applications
- Suggested by courts
- Brings generic drug products to market in a timely fashion

What are the Exceptions?

- Triggering Period Would not Start Until:
  - 30 Month Stay has Ended
  - Injunction Prohibiting Marketing Expired
  - Statutory Timeframes for RLD Exclusivity Expired

Response to Triggering Period

- 6 in favor
- 11 oppose
- 2 no comment

When Does Exclusivity Begin?

- "A" Court Decision
- First Commercial Marketing
- After the Triggering Period

What Can Start Exclusivity?

First Commercial Marketing Starts Exclusivity	1st Application PIV Eligible	A Court Decision Starts Exclusivity
	Another Application Receives TA	
1st Comm. Mkt. Or A Court Decision Starts Exclusivity	Starts Triggering Period-180 days	Exclusivity Not Triggered Within 180-day Period Exclusivity Lost

What is "A" Court Decision?

- Does not have to be a decision in the "first" applicant's law suit
- Can be a decision in a subsequent applicant's law suit

What if I Lose My Lawsuit?

- No longer eligible for exclusivity
- Subsequent applications may be approved

Can Exclusivity Extend Past the Patent Expiration?

No

When May Exclusivity be Waived?

- After the 180-day exclusivity period has been initiated by either first commercial marketing or a court decision
  - 1 in favor
  - 8 oppose
  - 10 no comment

What is Relinquishment?

- The applicant relinquishes eligibility for exclusivity.
- All subsequent applications may be approved

Multiple Strength/Drug Product Exclusivity

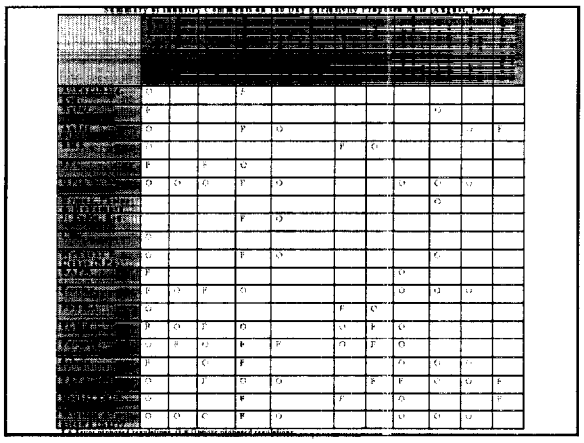
- Each strength of a drug product is independently eligible for exclusivity
  - 3 in favor
  - 0 oppose
  - 16 no comment

Proposed Implementation Plan

- Takes Effect 30 days after publication in FR
  - Applies to ANDAs pending as of the effective date
  - Applies to ANDAs submitted after the effective date
    - 0 in favor
    - 8 oppose
    - 11 no comment

What Does FDA Expect?

- Quality Applications
- Actively pursuing approval
- Actively seeking resolution of law suits
- Timely market entry



180-day News Update

- Mylan v. Shalala - January 4, 2000
  - No appeal
  - Guidance forthcoming